UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
MARK FALK
UNITED STATES MAGISTRATE JUDGE

USPO & COURTHOUSE
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NEWARK, NJ 07101
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July 15, 2008

LETTER ORDER

TO ALL COUNSEL OF RECORD

Re: Eli Lilly and Company v. Actavis Elizabeth LLC, et al.,
No. 07-3770 (DMC)

Dear Counsel:

Before the Court is a discovery dispute concerning the entry of a protective order. Defendants—Teva, Actavis, Apotex, Aurobindo, Mylan, Sandoz, and Sun (collectively, "defendants")—have moved for entry of an order with restrictions on in-house counsel. Plaintiff—Eli Lilly—has opposed the restrictions. The Court has received four letters on the dispute and considered them all.[1] Pursuant to Rule 78, the Court decides this application without oral argument. For the reasons that follow, the Court will not include defendants' restrictions in the protective order.

BACKGROUND

Eli Lilly brought this patent infringement action against defendants alleging infringement of U.S. Pat. No. 5,658,590 ("the '590 patent"). The '590 patent covers a method of using the drug atomoxetine for treating attention-deficit hyperactivity disorder ("ADHD"), marketed under the brand name Strattera®. Atomoxetine was originally known as tomoxetine (changed per FDA

[1] The letters the Court has considered are those dated June 6, 2008 (docket no. 159), June 12, 2008 (docket no. 160), June 27, 2008 (docket no. 168), and June 30, 2008 (docket no. 169).

request to avoid confusion with a similar sounding drug) and is sometimes still referred to as such. At the present, the parties have been attempting to negotiate a protective order to govern the disclosure of confidential material.

The discovery dispute in this case centers on a single provision in the protective order. Specifically, exhibit 3 to the defendants' June 12 letter (paragraph 4) states the contested provision as:

> The specified legal personnel…designated by the parties shall not: (1) be involved in the preparation or prosecution of any patent application that covers tomoxetine or atomoxetine compositions for the duration of the action…and for a period of at least two (2) years thereafter; or (2) disclose to the FDA any CONFIDENTIAL Discovery Material obtained as a result of this litigation.

(Letter brief from Lite, DePalma, Greenberg & Rivas of 6/12/08, Ex. 3, ¶ 4.)

Plaintiff contends that provision 1 in the above quoted paragraph, which precludes plaintiff's in-house counsel from prosecuting patent applications for the duration of this action and two additional years, is overbroad and unnecessary. Plaintiff argues that absent a showing a particularized harm, the provision cannot withstand the requirements of applicable case law. Plaintiff also argues that subsection 2, which prohibits disclosure of confidential material to the FDA, is duplicative and unwarranted.

Conversely, defendants argue that plaintiff's in-house counsel will not be able to "wall off his memory" when presenting formulated claims to the United States Patent Office. Defendants contend that plaintiff will suffer no prejudice from the provision and that plaintiff already agreed to the provision and is now "reneging." Defendants further contend that plaintiff's reluctance to enter into the order is for purposes of delay and to impede the progress of discovery.

ANALYSIS

A. Legal Standard

In patent cases, the law that applies to discovery issues is that of the regional circuit. See Computer Docketing Station Corp. v. Dell, Inc., 519 F.3d 1366, 1373 (Fed. Cir. 2008). Federal Rule of Civil Procedure 26(c) states: "The court may, for good cause, issue an order to protect a party." The Third Circuit has held that "good cause" is demonstrated, and a protective order is warranted, "when a party shows that disclosure will result in a clearly defined, specific and serious injury but that broad allegations of harm are not sufficient." Shingara v. Skiles, 420 F.3d 301, 306 (3d Cir. 2005) (citing Pansy v. Borough of Stroudsburg, 23 F.3d 772 (3d Cir. 1994)). The burden of showing good cause rests with the party seeking a protective order. See Cipollone v. Ligget Group, 785 F.2d 1108, 1114 (3d Cir. 1986).

B. The FDA Restriction

The parties have already agreed to a provision in the protective order, at paragraph 10, that limits the use of material obtained through discovery to the action at hand. This eliminates the need for an additional provision prohibiting the disclosure of information to the FDA. Simply stated, subsection (2) of paragraph 4 is redundant as any disclosure of information to the FDA would already violate the protective order. Defendants have articulated a legitimate concern regarding inadvertent disclosure of information. The proposed FDA restriction, however, would not guard against inadvertence any more than paragraph 10 and is unwarranted.

C. The Prosecution Restriction

The primary dispute over paragraph 4 is on the prosecution restriction that defendants propose. Defendants intend the prosecution restriction to run broadly and cover any and all patents where atomoxetine compositions are involved both for the life of the present action and two years into the

future.[2] Such a restriction is quite broad and not supported by a specific showing of good cause under the Third Circuit's standard.

In AFP Advanced Food Prods., LLC v. Snyder's of Hanover Mfg., the court struck down a similar prosecution restriction as overbroad. 2006 WL 47374, at *3-4 (E.D. Pa. Jan. 6, 2006). In that case, the defendant sought to prevent the plaintiff's counsel from engaging in patent prosecution relating to "low protein containing products…including cheese dips." The patent-in-suit concerned "Acidified Imitation Cheese Sauce" and the defendant's only basis for the restriction was the fear of inadvertent misuse of confidential information. See id. at *1-2. The court found that: "barring AFP's attorneys from prosecuting similar patents for two years following this suit, without some tangible reason or good cause…is the exact type of over broad and generalized fear rejected in Shingara, U.S. Steel[Corp. v. United States, 730 F.2d 1465 (Fed. Cir. 1984)], and In re Sibia Neurosciences." Id. at *2.

The same logic controls here. A prosecution restriction that covers any patent where any composition of atomoxetine is involved, not just a particular method of use, is analogous to a restriction on low protein containing products where the underlying patent was for a specific type of product, namely cheese sauce. Upon consideration of the submissions, the Court concludes that defendants have simply failed to carry their burden of showing a specific identifiable harm sufficient to enter their proposed order. See AFP Advanced Foods, 2006 WL 47374, at *3. Defendants' letter submission is vague and broadly asserts potential harm. They have not provided the Court will any

[2] Lilly has agreed that "it's in-house counsel (with access to confidential material) will not have patent prosecution responsibilities for current or future Lilly patent applications concerning atmoxetine formulations." (Letter brief from Eli Lilly dated 6/6/08 at 2.) The Court believes this provision is proper and should be included in any discovery confidentiality order entered.

reason to believe Lilly's in-house counsel will, intentionally or otherwise, disclose or rely on confidential information in any future activities. As such, they have failed to show good cause under Third Circuit law, and the restriction is unwarranted.[3]

CONCLUSION

The restrictions in the defendants' proposed protective order are overly broad and not supported by good cause. For that reason, the Court will not enter a confidentiality order with the proposed restrictions. The parties are directed to confer and submit a proposed discovery confidentiality order, consistent with this Letter Order, within ten (10) days.

SO ORDERED.

s/Mark Falk
MARK FALK
United States Magistrate Judge

Orig.: Clerk of the Court
cc: Hon. Dennis M. Cavanaugh, U.S.D.J.
All Parties
File

[3] The parties have also vaguely raised whether Lilly lawyer Mark Stewart should be permitted to review defendants' confidential information. To the extent defendants seek to exclude Mr. Stewart solely on the basis of his "limited patent prosecution responsibilities," that would appear, at first blush, to be "the type of generalization counseled against in U.S. Steel." In re Sibia Neurosciences, 132 F.3d 50, 1997 WL 688174, at *3 (Fed. Cir. Oct. 22, 1997) (table). However, this dispute, to the extent it actually is one, is not briefed sufficiently for the Court to decide. Between the four letters submitted, discussion of Mr. Stewart's involvement is limited to two paragraphs. There is no detailed argument and no citation to legal authority. To the extent the parties feel this issue must be addressed by the Court, they may raise it with the Court in accordance with the Local Civil Rules.